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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,165	06/12/2000	PATRICK W. GRAY	27866/34810	7556
7590 03/09/2004				
DAVID A GASS MARSHALL O'TOOLE GERSTEIN MURRAY & BORUN 633 SEARS TOWER 233 SOUTH WACKER DRIVE CHICAGO, IL 60606-6402			EXAMINER LI, BAO Q	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



## Office Action Summary

### Application No.

09/509,165

### Applicant(s)

GRAY ET AL.

### Examiner

Bao Qun Li

### Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 26-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 27-29, 32-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26,30,31 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.



### **DETAILED ACTION**

Claims 1-14, 26-43 are pending. Claims 26, 30-31 and 38-43 are considered before the examiner, Claims 1-14, 27-29 and 32-37 are withdrawn from the consideration.

### **PETITION**

The petition under 1.181 filed on October 30, 2003 has been granted. In view of the decision, the finality of the Office Action mailed 27, August 2003 is withdrawn. Claim 1 is withdrawn from the Group II. Invention of group V and VI (Claims 13 and 14) are rejoined. Claims 40-43 are rejoined with the ejected group VII, claims 26, 38-31.

In view of the petition granted on January 21, 2004, previous Final Office Action mailed on August 27, 2003 is withdrawn. A new Non-Office Action based on the newly rejoined claims 26, 30-31 and 38-43 follows:

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 26, 30-31 and 38-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a monoclonal antibody against MDC to block the CCR4 mediated cellular response in vitro, does not reasonably provide enablement for using any or all MDC or TARC antagonist for treating any or all allergic reaction in a subject, especially for human being. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.
3. The test of scope of enablement is whether one skilled in the art could make and use the claimed invention from the disclosure in the application coupled with information known in the art would undue experimentation (See *United States v. Theketrone Inc.*, 8USPQ2d 1217 (fed Cir. 1988)). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. These factors were outlined in Ex parte



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Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors are analyzed according the situation of the present application.

4. 1) & 2) State of art and unpredictability. It is known in the art that allergy is caused by the infiltration of eosinophils. MDC and TARC share same receptor CCR4. However, this receptor is not expressed in eosinophil. It has been reported that the chemotaxis of eosiphile induced by MDC is a CC chemokine receptor CCR3 and CCR4 independent as evidenced by Bocher et al. (J. Allergy Clin. Immunol. 1999, Vol. 103, pp. 527-532). As MDC induced the eosinophil accumulation is a CCR4 independent, it is unpredictable whether MDC or TARC antagonist that blocks CCR4 is able to inhibit an allergic reaction mediated by eosinophils. Recently, it is reported by Conrey et al. (J Leukoc Biol. 2003, Vol. 74(4), pp. 558-63) that while CC chemokine receptor 4 (CCR4) shows selectivity for the recruitment of memory T cell subsets, including those of the T helper cell type 2 (Th2) phenotype and in humans, CCR4+ T cells are recruited to the asthmatic lung in response to allergen challenge; however, the contribution of this pathway to allergic disease remains uncertain. Because blockade of CCR4 with a specific antibody resulted in only minor changes in numbers of CCR4+ Th cells in the bronchoalveolar lavage fluid of allergen-challenged guinea pigs and failed to inhibit the generation of eotaxin/CC chemokine ligand (CCL)11 or macrophage-derived chemokine/CCL22 or the recruitment of inflammatory leukocytes to the lung. These data suggest that although CCR4 was originally proposed as a marker of Th2 status, antigen-specific Th2 cells are recruited to the lung predominantly by other pathways. This study casts doubts on the validity of CCR4 as a therapeutic target in the treatment of asthma (See abstract).

5. 3) & 4) Number of working examples and amount of guidance. The specification only teaches that human MDC or TARC share same receptor CCR4 and monoclonal antibodies against human MDC, 252Y and 252Z inhibit CCR4 mediated biological activity. However, Applicants does not teach that any MDC antagonist or TARC antagonist is able to inhibit an allergic reaction in vivo. The specification lack the evidence that MDC or TACR antagonist, or any fragment thereof is able to inhibit the allergic reaction. The specification is deficient for teaching use of any polypeptide listed in claims 40 or 43 to inhibit the allergic reaction in vitro and in vivo. Applicants do not provide adequate guidance for practicing the claimed invention too.



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6. 5) Scope of the claims. The scope of claims read broad with a method for treating allergic reaction by using any or all MDC or TARC antagonist.
7. 6) & 7) Nature of invention and lever of the skill in the art. The nature of the invention is related to an in vivo application of MDA or TARC antagonist for treating any allergic reaction. The level of the skill is high. The in vitro experiment cannot be extrapolated into a result from an an-vivo test.
8. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

***Conclusion***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

February 26, 2004

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1000  
3/8/04



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